UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,825	01/15/2002	Rodrigo F. Chaqui	66043	8611

45323 7590 01/23/2006

NATIONAL INSTITUTES OF HEALTH
C/O VENABLE LLP
P. O. BOX 34385
WASHINGTON, DC 20043-9998

EXAMINER	
DAVIS, MINH TAM B	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 01/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/743,825	CHAQUI ET AL.	
	Examiner	Art Unit	
	MINH-TAM DAVIS	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,3,5-8,10-19,25 and 27-34* is/are pending in the application.

4a) Of the above claim(s) *6-8 and 13-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,3,10-12,17-19,25 and 27-34* is/are rejected.

7)☒ Claim(s) *5* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *08/02/05*.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Accordingly, claims 2, 3, 5, 10-12, 17-19, 25, 27-34 are being examined.

The following are the remaining rejections.

This application contains claims drawn to an invention nonelected with traverse in Paper of 02/03/04. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

OBJECTION

1. Claim 18 is objected to for the use of the abbreviation "nt".

2. Claim 5 appears to be free of prior art but is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent forms.

REJECTION UNDER 35 USC 112, FIRST PARGRAPH, NEW MATTER, NEW REJECTION

Claim 18 is rejected under 35 USC 112, first paragraph, as the specification does not contain a written description of the claimed invention.

The limitation of a fragment of SEQ ID NO:1 of "about 20 to about 30 nucleotides" claimed in Claim 18 has no clear support in the specification and the claims as originally filed.

A review of the specification discloses support for primers of various sizes, for example, SEQ ID NO:7 consisting of 22 nucleotides, SEQ ID NO:8 consisting of 21 nucleotides, SEQ ID NO:10 consisting of 20 nucleotides (See sequence listing).

There is nothing in the specification to suggest a size range of about 20 to about 30 nucleotides.

The subject matter claimed in claim 18 broadens the scope of the invention as originally disclosed in the specification.

REJECTION UNDER 35 USC 112, FIRST PARGRAPH, WRITTEN DESCRIPTION

Claims 2, 3, 10-12, 17, 19, 25, 27-34 remain rejected under 112, first paragraph, for lack of a clear written description of a nucleic acid molecule that comprises a sequence that is completely complementary to the full length sequence of SEQ ID NO:1, or the sequence of nucleotides 77-1753 of SEQ ID NO:1, for reasons already of record in paper of 09/01/05.

Applicant argues that Applicant was in possession of the genus of DNA that comprise SEQ ID NO:1, or its coding region of nucleotides 77-1753, and that the claims do not read on genomic DNA.

Applicant's arguments in paper of 12/01/05 have been considered but are found not to be persuasive for the following reasons:

The issue is not whether Applicant was in possession of the genus of DNA that comprise SEQ ID NO:1, which is a full length cDNA sequence, or its coding region of nucleotides 77-1753.

Rather, **the issue is that the claims encompass a genus of unknown sequences of any size, attached to a fragment of any size, wherein said fragment is completely complementary to a full length sequence comprising SEQ ID NO:1, or** its coding region of nucleotides 77-1753.

The specification and the claims however do not describe the claimed nucleic acids in a manner that satisfies the standards as set forth the examples of Lilly and Enzo. The recited single polynucleotide sequence, SEQ ID NO:1 and its primers consisting of SEQ ID NO:7, 8 or 10, is not a representative number of species. Further, the specification does not describe "structural features common to the member of the genus, which features constitute a substantial portion of the genus". Moreover, the specification fails to describe characteristics coupled with known or disclosed correlation between structure and function.

One would conclude that Applicant did not have possession of the claimed genus of nucleic acids at the time of filing. Further, since the specification fails to adequately describe the product that is used in the claimed method, it also fails to adequately describe the claimed method.

REJECTION UNDER 35 USC 112, FIRST PARGRAPH, SCOPE

A. Claims 2, 3, 10-12, 17, 19, 25, 27-34 remain rejected under 112, first paragraph, for lack of enablement of a nucleic acid molecule that comprises a sequence that is completely complementary to the full length sequence of SEQ ID NO:1, or its coding region of nucleotides 77-1753, for reasons already of record in paper of 09/01/05.

Applicant argues that the Examiner has failed to establish a prima facia case that the instant specification fails to enable the claims which recite a sequence comprising SEQ ID NO:1 or its coding region thereof.

Applicant's arguments in paper of 12/01/05 have been considered but are found not to be persuasive for the following reasons:

The issue is not whether the specification is enabled for a DNA that comprises SEQ ID NO:1, which is a full length cDNA sequence, or its coding region of nucleotides 77-1753.

Rather, the issue is that **the claims encompass a genus of unknown sequences of any size, attached to a fragment of any size, wherein said fragment is completely complementary to a full length sequence comprising SEQ ID NO:1, or** its coding region of nucleotides 77-1753.

One would not know how to make the claimed nucleic acids such that they would function as claimed, in view of the unpredictability of protein chemistry, as taught by Bowie, Burgess et al, Lazar et al, Tao et al, and Gillie et al, all of record, wherein said

unpredictability applies as well to the claimed polynucleotides, because polynucleotide sequences encode proteins.

Further, Applicant asserts that at the suggestion of the Examiner in the informal telephonic interview of 08/02/05, claims 17, 18, 19, 27, 30 have been amended to clarify that a sequence which is "completely complementary" to a second sequence is complementary to the complete length of the second sequence".

It is noted that Applicant misunderstood the Examiner's suggestion in the telephonic interview of 08/02/05. The Examiner suggested that Applicant amends the claims to recite for example "a nucleic acid molecule that comprises the sequence of SEQ ID NO:1, or a complete full length complement of said nucleic acid molecule" to obviate the rejection.

B. If Applicant could overcome the above 112, first paragraph, claims 11, 32 are still rejected under 112, first paragraph, for lack of enablement of a method for detecting prostate cancer, using a sample "from prostate tissue", for reasons already of record in paper of 09/01/05.

Applicant argues that amendment to recite "a sample from prostate tissue" would obviate the rejection.

Applicant's arguments in paper of 12/01/05 have been considered but are found not to be persuasive for the following reasons:

The claims still read on a sample of cells metastasized from primary prostate cancer tissue.

It is however unpredictable that the metastasized prostate cancer cells still express the claimed sequence, in view that expression of a sequence could be lost during progression toward metastasis, as taught by Kibel et al, Zhau et al, Cheung et al, and Ren et al, all of record.

REJECTION UNDER 35 USC 102(b)

1. Claims 17, 27 remain rejected under 35 USC 102(b) as being anticipated by Boehringer or Hudson for reasons already of record in paper of 09/01/05.

Applicant argues that neither the references disclose the nucleic acid containing the sequence represented by SEQ ID NO:1 or the coding sequences thereof.

Applicant's arguments in paper of 12/01/05 have been considered but are found not to be persuasive for the following reasons:

It is noted that the claims encompass a fragment of any size, or unknown sequences attached to a fragment of any size, wherein said fragment is completely complementary to a full length sequence comprising SEQ ID NO:1, or its coding region of nucleotides 77-1753, via said fragment.

The random primers taught by Boehringer or the sequence taught by Hudson clearly contains a sequence that would be completely complementary to the full length SEQ ID NO:1.

All the limitations are met.

2. Claim 18 remains rejected under 35 USC 102(b) as being anticipated by Boehringer, for reasons already of record in paper of 09/01/05.

Applicant argues that the random primers taught by the art contain only 6 nucleotides each, and do not contain the about 20 to about 30 nucleotides recited in claim 18.

Applicant's arguments in paper of 12/01/05 have been considered but are found not to be persuasive for the following reasons:

It is noted that a nucleic acid molecule that consists of a sequence that is completely complementary to a fragment of about 20 to about 30 nucleotides of SEQ ID NO:1 does not have to contain about 20 to about 30 nucleotides.

The random hexamer primers taught by Boehringer clearly would be completely complementary to a fragment of about 20 to about 30 nucleotides of SEQ ID NO:1.

All the limitations are met.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JEFFREY SIEW can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,

MINH TAM DAVIS, Ph.D.

January 05, 2006

SUSAN UNGAR, PH.D
PRIMARY EXAMINER